



**UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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|-----------------|-------------|----------------------|---------------------|

09/255,655 02/23/99 VIGH

M 02405.0167

EXAMINER

HM12/0302

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OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

03/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory ActionApplication No.
09/255,655Applicant(s)
Vigh et al.Examiner
Howard OwensGroup Art Unit
1623**THE PERIOD FOR RESPONSE:** [check only a) or b)]

- a) ☒ expires 6 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Dec 27, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☐ The proposed amendment(s):
- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
 - ☐ will not be entered because:
 - ☐ they raise new issues that would require further consideration and/or search. (See note below).
 - ☐ they raise the issue of new matter. (See note below).
 - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See response to supplemental response.

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: NONE

Claims objected to: _____

Claims rejected: 1-12

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Other

Response to Supplemental Response

35 U.S.C. § 103

Applicant's arguments filed 12/27/00 in response to the rejection of claims 1-12 under 35 U.S.C. 103(a), have been fully considered but they are not persuasive.

Applicant asserts that "As presently understood, the Office is relying on the principle of inherency", as acknowledged by applicant's representative the 35 U.S.C. 103 rejection of record does not mention any principle of inherency. The mention of inherency during an interview with applicant's representative was an additional afterthought provided by Examiner Geist with regards to the use of the invention but does not serve as the basis for supporting the obviousness rejection.

Applicant contends that there is nothing in the prior art relied on by the Examiner that shows or suggests that a person of ordinary skill in the art would recognize or appreciate that D-tagatose will "selectively" induce butyrate production and "selectively" stimulate the growth of Lactobacilli and lactic acid bacteria in the human colon. With regards to the "selective" production of butyrate, the prior art (Mortensen et al. and Macfarlane et al) has set forth that monosaccharides or ketohexoses serve as a substrate for the production of Short Chain Fatty Acids such as butyrate and also allow for the growth of commensalistic indigenous flora such as Lactobacilli. Mortensen et al. teaches that a substantial capacity for enhancement of the Short Chain Fatty Acid (propionate and butyrate specifically) production is available when sufficient amounts of an appropriate substrate are present (p. 324, paragraphs 2); therefore, D-tagatose is not alone in the production of butyrate in the human colon; moreover, Zehner clearly teaches that the state of the art has recognized the fermentation of D-tagatose by human microflora, specifically *Lactobacillus casei* (col.2, lines 56-67). Zehner also teaches that this fermentation could be beneficial if it is slow in the human gut and produces non-caloric metabolites (col. 2, line 67 - col.3, line 3).

Art Unit 1623

The benefits of SCFA's such as butyrate are well known in the art of human nutrition, thus applicant's contention that one of skill in the art provided with a compound that is known to produce SCFA's such as butyrate from *Lactobacillus* microflora, specifically *L. casei*, would not have a reasonable expectation of success in the use of that compound to produce butyrate is not convincing and the finality of the last office action is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Tuesday-Friday 9 a.m.-6:30 p.m. (EST).

If attempts to reach the examiner by telephone are unsuccessful, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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Secure and confidential access to patent application status is now available; see <http://www.uspto.gov/ebs/index.html> for more information.

Applicant(s) may pay patent maintenance fees, non-filing application fees and maintain USPTO accounts through <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm>


GARY GEIST
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